Trial Progress – Still Climbing!

Trial enrollment numbers reflect study information as of the September 30, 2014 Trial Progress Report

Open Studies

- CTN 0050 – Long Term Follow-up to the CTN 0027 (START) Study. Enrolled 872 (Original N=1,267 START Study participants).
- CTN 0056-Ot – Testing and Linkage to HIV Care in China. Enrolled 431 (N=360).
- CTN 0057-Ot – SBIRT-PC (Screening, Brief Intervention, and Referral to Treatment in Primary Care). Enrolled 72 (N=200).
- CTN 0059 – TAPS Tool (Tobacco, Alcohol, Prescription Medications, and Substance Use/Misuse Brief Screen/Assessment). Enrolled 381 (N=2000).

Total Enrolled All Studies: 17,426

News from the CTN Nodes

Southern Consortium Node

Therese Killeen, PhD, Co-Investigator, presented a six hour workshop on "Supervision using an MI Approach" at the 8th annual Georgia School of Addiction Studies, in Savannah, GA. The theme of this year’s School was “Prevention, Treatment, and Recovery.” This is a week-long annual conference highlighting evidence based practice workshops.

Executive Committee (EC)

The EC held a webinar on Thursday, September 4th entitled “What is the difference between adaptive designs, adaptive treatment strategies, and enrichment strategies?” The speaker was Paul Wakim, PhD, Senior Statistician at NIDA. "Adaptive designs," "adaptive treatment strategies," and "enrichment strategies" were described, and the relevance to our research was discussed. CTN thanks go to Paul Wakim and the EC for providing this informative seminar!

CTN Study News


Among the studies referenced is Project AWARE, led by Dr. Lisa Metsch of the Florida Node Alliance and Dr. Grant Colfax of the Western States Node. (See the Dissemination Library article in this issue for a link). Congratulations AWARE Team!

Columbus Day Schedule

NIDA’s CCTN office will be closed Monday, October 13, 2014 in observance of the Columbus Day holiday.

NIDA CCC and DSC offices at EMMES will be open on October 13. The DSC Help Desk staff will be available that day.

CTN 0047 SMART-ED now on NIDA Datashare!
The datasets for this and many other CTN studies are available at http://datashare.nih.gov/
Clinical Coordinating Center

CTN Web Seminar Series

If you missed the September 10, 2014 training on Certificates of Confidentiality (CoC) you can still watch the webinar at the CTN Dissemination Library’s website at: http://ctndisseminationlibrary.org/display/1100.htm. This informative and engaging session was presented by NIDA’s Dr. Nadine Rogers and Ms. Natisha Rowe. Participants had the opportunity to ask questions pertaining to all aspects of this required protection for our participants. CoC application requirements, process, and how these relate to our CTN studies were discussed in detail. Ninety participants joined the live discussion!

Upcoming in the Series

On October 1, 2014 at 1:00 pm ET, Julia Gorey, JD, Public Health Analyst in the Division of Policy and Assurances, Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS), will discuss the requirements and process for obtaining approval to conduct research with prisoners as outlined in current regulations and protections (45 CFR part 46). To register for this event, please use the following link: https://cc.readytalk.com/r/q6yyvebrvlmc&com.

Upon completing your registration, you will receive an email confirmation that will include the dial-in number, passcode, and a unique link to be used when joining this webinar. All individuals are encouraged to register even if planning to participate as a group, as this will ensure that everyone receives materials and updates before the webinar.

If you would like to participate in this webinar or future trainings and have not signed up, please contact CTN CCC Training Coordination at ctntraining@emmes.com to request registration assistance and to be added to the mailing list.

Reminder: The CTN GCP training Website is available to help prepare CTN staff to conduct research from development through closeout.

The CCC values your suggestions for CTN Training! Follow this link to submit to our CTN Training Suggestion Box: https://www.surveymonkey.com/s/CTNTrainingSuggestionBox.

“How to” corner

Thanks to a suggestion from Brooke Heidenfelder, PhD, the project director for the CTN 0057-Ot study, the CTN Bulletin will periodically include a “How To” feature. This section will provide an opportunity for all of us to share our experience and solutions that address challenges we all face in conducting clinical trials, or dealing with clinical problems.

The next installment will be on hi-tech tools. Brooke will share some hints for addressing the challenges faced when tablets and smart phones are added to the research project. If you would like to share an example of how you addressed a problem with these tools, please send a description to Michele Straus at mstraus@nida.nih.gov.

Here’s the first one: Ever have a patient in your clinic have an adverse event to a medication that isn’t reported anywhere you can find? If the patient is also a study participant report the event through the study’s adverse event reporting system. If not, use MedWatch: The FDA Safety Information and Adverse Event Reporting Program

This system provides an approach to report problems for a wide range of medical products. Links to FDA approved safety information can also be found at: http://www.fda.gov/safety/medwatch/default.htm

7th Annual Conference on the Science of Dissemination and Implementation:

Transforming Health Systems to Optimize Individual and Population Health
December 8-9, 2014
Bethesda North Marriott Hotel & Conference Center

The conference aims to grow the research base by bridging the gap between evidence, practice, and policy in health and medicine.

What’s New in the CTN Dissemination Library?

Three new outcomes papers were recently added – find out what these three studies have added to the field’s knowledge base below, and then read about a new study, CTN 0053, looking at cannabis cessation.

CTN 0036-Ot: Epidemiology and Ethnographic Survey of “Cheese” Heroin Use Among Hispanics in Dallas County:

Characteristics of Mexican and Mexican American Adolescents in Treatment for “Cheese” Heroin Use.

Participants reported, on average, first using cheese heroin at age 13.5 years and daily use at age 14.2 years. The majority (74%) reported a previous overdose. The self-reported brief time period from first use to daily use strongly suggests the need for early prevention and rapid intervention efforts after first use of heroin in this population. [read more]

**CTN 0047: Screening Motivational Assessment and Referral to Treatment in Emergency Departments (SMART-ED):**


Follow-up rates were 89%, 86%, and 81% at 3, 6, and 12 months, respectively. There were no significant differences between groups in self-reported days using the primary drug, days using any drug, or heavy drinking days. The findings of this study suggest that even a relatively robust brief intervention is unlikely to be useful as a general strategy for ED patients with relatively severe drug problems and other life challenges. [read more]

**Project AWARE (adaptation of CTN-0032: HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the US):**


Analysis of the results found that risk reduction counseling in conjunction with a rapid HIV test did not significantly affect sexually transmitted infection acquisition among STD clinic patients, suggesting no added benefit from brief patient-centered risk-reduction counseling in that setting. Post-test counseling for patients testing HIV-positive remains essential for addressing psychological needs and for providing and ensuring follow-through with medical care and support. [read more]

**CTN 0053: Achieving Cannabis Cessation—Evaluating N-Acetylcysteine Treatment (ACCENT):**


This 12-week, intent-to-treat, randomized controlled trial will evaluate the impact of N-Acetylcysteine 1200 mg versus matched placebo twice daily, added to compliance enhancement and contingency management interventions, on cannabis use among treatment-seeking adults (ages 18-50) with cannabis use disorders. [read more]

The CTN Dissemination Library is hosted by the Pacific Northwest Node of the Clinical Trials Network. Send questions, comments, and submissions to info@ctndisseminationlibrary.org.

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**Farewell to our Synergy Colleagues, and Welcome to LMCl**

As we announced at the 2014 Steering Committee Meeting, Synergy Enterprises, Inc. will no longer coordinate our meetings and phone calls (and so much more!). We cannot thank them enough for their dedication and support over the past decade, but congratulate them on their graduation to bigger and better things.

Welcome aboard to Leed Management Consulting, Inc. (LMCi), our new contractor for logistical support! LMCI will be working closely with NIDA and Synergy staff to ensure a smooth transition. All CTN committee and SIG conference call numbers will remain the same! Please contact Quandra Scudder scudderq@nida.nih.gov if you have questions.

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**From our ATTC Colleagues**

**Upcoming Seminar**

The National Hispanic and Latino ATTC is hosting a conference titled “Integrating Research, Education, and Services to Reduce Behavioral Health Disparities in Hispanic and Latino Populations” on October 8-9th, 2014 at the University of Texas at Austin. The Florida Node Alliance is a co-sponsor. Registration is open! Please visit: http://www.hispaniclatinoattcconference.com/

**Free Webinar!**

"Demystifying Opioid Addiction Treatment: An Introduction to the NIDA/SAMHSA Blending Initiative Buprenorphine Treatment Blending Product"
ATTC Network's Third Thursday iTrainings

Special Announcement

The CTN Bulletin has always been a great way to find out what's going on across the network. Now, when we see each other so seldom, it continues to help us keep in touch across the miles. Your news is important to us all in so many ways—A heartfelt thank you to all who contribute! Please send all Bulletin articles to Michele Straus mstraus@nida.nih.gov.

Note: A new distribution process will be in place for the next CTN Bulletin!

We are creating a Listserv to make sure that the CTN Bulletin is available to all CTNers who would like to receive it. Please make sure that the two listservs are identified as “not spam” so you continue to receive the CTN Bulletin!

Here are the titles of the two LISTSERVs:

CTN-BULLETIN-CALL-FOR-ARTICLES
&
CTN-BULLETIN-DISTRIBUTION

You can always opt out of either list, or just send an email.
Thank you for your help in making the CTN Bulletin a great resource to our CTN community!

News from NIDA

Funding Opportunities-Reminder!!!

RFA-DA-15-008

The National Institute on Drug Abuse (NIDA) has recently released a Request for Applications (RFA) http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-15-008.html. This Funding Opportunity Announcement (FOA) invites applications from clinical investigators to participate in the National Drug Abuse Treatment Clinical Trials Network (CTN).

RFA-DA-15-010


A NIH Guide Notice NOT-OD-14-120 was also released. This notice describes the solicitation and provides the necessary links and information. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-120.html)

The deadline for contract proposal submissions is Wednesday, November 5, 2014, at 4:30 p.m. ET and submissions must be on paper (not electronic, not through Grants.gov). Applicants are advised to follow the directions in the solicitation very carefully, and to address a topic listed in the solicitation.

Omnibus SBIR opportunities (http://grants.nih.gov/grants/guide/pa-files/PA-14-071.html) are still available, and STTR grant solicitations (http://grants.nih.gov/grants/guide/pa-files/PA-14-072.html) are open for the next receipt date of December 5, 2014. If you plan on an investigator-initiated submission, please use these announcement links.


Updates for this Bulletin should be sent to

Michele Straus at mstraus@nida.nih.gov

Connect with NIDA through: